REMARKS

In the Office Action dated October 3, 2003, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the pending claims, claims 6-11 and 15-29, represents the following five separate and distinct inventions:

Group I.	Claims 6 to 11, 20, 23, 24 and 28, drawn to a recombinant leptin receptor, classified in class 530, subclass 350.
Group II.	Claims 15, 16, 25 and 26, drawn to an antibody to a leptin receptor, classified in class 530, subclass 388.22.
Group III.	Claims 17, 18 and 21, drawn to a ligand, classified in class 530, subclass 399.
Group IV.	Claims 19 and 27, drawn to a binding assay, classified in class 435, subclass 7.21.
Group V.	Claims 22 and 29, drawn to a method of treatment by administering a receptor protein, classified in class 514, subclass 2.

The Examiner alleges that Groups I-V are distinct, each from the other. In the first instance, the Examiner contends that the receptor proteins of Group I, the antibodies of Group II and the ligands of Group III are three chemically distinct and structurally unrelated compounds, each of which can be made and used without the others. These three groups of compounds lack unity of invention because they do not have a common utility that is based upon a shared feature or combination of features lacking from the prior art. Furthermore, the Examiner states that Group I is related to each of Groups IV and V as product and process of use. However, the Examiner contends that the Groups I and Groups IV-V are distinct because the analytical methods of Group IV and the methods of treatment of Group V are two materially different methods of using the proteins of Group I, and because they achieve different objectives through different method steps. The Examiner concludes that because Groups I-V are distinct for the

reasons given above and have acquired a separate status in the art, as shown by their different classification, restriction for examination purposes as indicated is proper.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group I, Claims 6 to 11, 20, 23, 24 and 28, drawn to a recombinant leptin receptor, classified in class 530, subclass 350, for continued prosecution. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

Applicants respectfully submit that Groups I-III are related to each other, because the antibodies of Group II are directed against the proteins of Group I, and the ligands of Group III bind to the proteins of Group I. Both the antibodies of Group II and the ligands of Group III can be used for the purification, detection, or modulation of the function of the proteins of Group I.

Clearly, Groups I-III are related and not independent. These groups are merely different aspects united under a single inventive concept.

Applicants submit, and as the Examiner has admitted, that Group I is related to Groups IV and V as product and process of use. The methods of Groups IV and V merely teach how to use the proteins of Group I. Thus, Groups I and Groups IV and V are also different aspects of a single invention.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

The Examiner also states that the inventions have acquired a separate status in the art as evidenced by the separate classification and recognized divergent subject matter and would require independent searches. Thus, the Examiner concludes that restriction for examination purposes is proper.

Reliance on the supposed classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as

evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade

and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs, or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

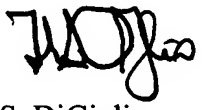
All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the

Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined five groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



Frank S. DiGiglio
Registration No. 31,346

SCULLY, SCOTT, MURPHY & PRESSER
400 Garden City Plaza
Garden City, New York 11530
(516) 742-4343

XZ:ab